REGULATIONS

Excerpt from

40 CFR Part 152

Pages 5 - 10

Pesticide Registration and Classification Procedures

The U. S. Environmental Protection Agency is required under the Federal Insecticide, Fungicide, and Rodenticide Act to register all pesticides available for use in the United States. This section sets forth the procedures, requirements, and criteria for registration and reregistration of pesticide products, and regulatory activities affecting registration. Testing must be in compliance with Good Laboratory Practices (40 CFR Part 792).

SUBCHAPTER E—PESTICIDE PROGRAMS

PARTS 150–151 [RESERVED]

PART 152—PESTICIDE REGISTRATION AND CLASSIFICATION PROCEDURES

Subpart A—General Provisions

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Subpart I—Classification of Pesticides

AUTHORITY: 7 U.S.C. 136–136y; Subpart U is also issued under 31 U.S.C. 9701.

Subpart A—General Provisions

SOURCE: 53 FR 15975, May 4, 1988, unless otherwise noted.

§ 152.1 Scope.

Part 152 sets forth procedures, requirements and criteria concerning the registration and reregistration of pesticide products under FIFRA sec. 3, and for associated regulatory activities affecting registration. These latter regulatory activities include data compensation and exclusive use (subpart E), and the classification of pesticide uses (subpart I).

[53 FR 15975, May 4, 1988, as amended at 60 FR 32096, June 19, 1995]

§ 152.3 Definitions.

Terms used in this part have the same meaning as in the Act. In addition, the following terms have the meanings set forth in this section.

(a) *Act* or *FIFRA* means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136–136y).

(b) *Active ingredient* means any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant within the meaning of FIFRA sec. 2(a).

(c) *Acute dermal* LD_{50} means a statistically derived estimate of the single dermal dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

(d) *Acute inhalation* LC_{50} means a statistically derived estimate of the concentration of a substance that would cause 50 percent mortality to the test population under specified conditions.

(e) *Acute oral* LD_{50} means a statistically derived estimate of the single oral dose of a substance that would cause 50 percent mortality to the test population under specified conditions.

(f) *Administrator* means the Administrator of the United States Environmental Protection Agency or his delegate.

(g) *Agency* means the United States Environmental Protection Agency (EPA), unless otherwise specified.

(h) *Applicant* means a person who applies for a registration, amended registration, or reregistration, under FIFRA sec. 3.

(i) *Biological control agent* means any living organism applied to or introduced into the environment that is intended to function as a pesticide against another organism declared to be a pest by the Administrator.

(j) *Distribute or sell* and other grammatical variations of the term such as ''distributed or sold'' and ''distribution or sale,'' means the acts of distributing, selling, offering for sale, holding for sale, shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any State.

(k) *End use product* means a pesticide product whose labeling

(1) Includes directions for use of the product (as distributed or sold, or after combination by the user with other substances) for controlling pests or defoliating, desiccating, or regulating the growth of plants, and

(2) Does not state that the product may be used to manufacture or formulate other pesticide products.

(l) *Final printed labeling* means the label or labeling of the product when

distributed or sold. Final printed labeling does not include the package of the product, unless the labeling is an integral part of the package.

(m) *Inert ingredient* means any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product.

(n) *Institutional use* means any application of a pesticide in or around any property or facility that functions to provide a service to the general public or to public or private organizations, including but not limited to:

(1) Hospitals and nursing homes.

(2) Schools other than preschools and day care facilities.

(3) Museums and libraries.

(4) Sports facilities.

(5) Office buildings.

(o) *Manufacturing use product* means any pesticide product that is not an end-use product.

(p) *New use,* when used with respect to a product containing a particular active ingredient, means:

(1) Any proposed use pattern that would require the establishment of, the increase in, or the exemption from the requirement of, a tolerance or food additive regulation under section 408 or 409 of the Federal Food, Drug and Cosmetic Act;

(2) Any aquatic, terrestrial, outdoor, or forestry use pattern, if no product containing the active ingredient is currently registered for that use pattern; or

(3) Any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms.

(q) *Operated by the same producer,* when used with respect to two establishments, means that each such establishment is either owned by, or leased for operation by and under the control of, the same person. The term does not include establishments owned or operated by different persons, regardless of contractural agreement between such persons.

(r) *Package* or *packaging* means the immediate container or wrapping, including any attached closure(s), in which the pesticide is contained for distribution, sale, consumption, use, or storage. The term does not include any shipping or bulk container used for transporting or delivering the pesticide unless it is the only such package.

(s) *Pesticide* means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, other than any article that:

(1) Is a new animal drug under FFDCA sec. 201(w), or

(2) Is an animal drug that has been determined by regulation of the Secretary of Health and Human Services not to be a new animal drug, or

(3) Is an animal feed under FFDCA sec. 201(x) that bears or contains any substances described by paragraph (s)(1) or (2) of this section.

(t) *Pesticide product* means a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold. The term includes any physical apparatus used to deliver or apply the pesticide if distributed or sold with the pesticide.

(u) *Residential use* means use of a pesticide directly:

(1) On humans or pets,

(2) In, on, or around any structure, vehicle, article, surface, or area associated with the household, including but not limited to areas such as non-agricultural outbuildings, non-commercial greenhouses, pleasure boats and recreational vehicles, or

(3) In any preschool or day care facility.

§ 152.5 Pests.

An organism is declared to be a pest under circumstances that make it deleterious to man or the environment, if it is:

(a) Any vertebrate animal other than man;

(b) Any invertebrate animal, including but not limited to, any insect, other arthropod, nematode, or mollusk such as a slug and snail, but excluding any internal parasite of living man or other living animals;

(c) Any plant growing where not wanted, including any moss, alga, liverwort, or other plant of any higher

order, and any plant part such as a root; or

(d) Any fungus, bacterium, virus, or other microorganisms, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs (as defined in FFDCA sec. 201(g)(1)) and cosmetics (as defined in FFDCA sec. 201(i)).

§ 152.8 Products that are not pesticides because they are not for use against pests.

A substance or article is not a pesticide, because it is not intended for use against ''pests'' as defined in § 152.5, if it is:

(a) A product intended for use only for the control of fungi, bacteria, viruses, or other microorganisms in or on living man or animals, and labeled accordingly.

(b) A product intended for use only for control of internal invertebrate parasites or nematodes in living man or animals, and labeled accordingly.

(c) A product of any of the following types, intended only to aid the growth of desirable plants:

(1) A fertilizer product not containing a pesticide.

(2) A plant nutrient product, consisting of one or more macronutrients or micronutrient trace elements necessary to normal growth of plants and in a form readily usable by plants.

(3) A plant inoculant product consisting of microorganisms applied to the plant or soil for the purpose of enhancing the availiability or uptake of plant nutrients through the root system.

(4) A soil amendment product containing a substance or substances added to the soil for the purpose of improving soil characteristics favorable for plant growth.

(d) A product intended to force bees from hives for the collection of honey crops.

§ 152.10 Products that are not pesticides because they are not deemed to be used for a pesticidal effect.

A product that is not intended to prevent, destroy, repel, or mitigate a pest, or to defoliate, desiccate or regulate the growth of plants, is not considered to be a pesticide. The following types of products or articles are not considered to be pesticides unless a pesticidal claim is made on their labeling or in connection with their sale and distribution:

(a) Deodorizers, bleaches, and cleaning agents;

(b) Products not containing toxicants, intended only to attract pests for survey or detection purposes, and labeled accordingly;

(c) Products that are intended to exclude pests only by providing a physical barrier against pest access, and which contain no toxicants, such as certain pruning paints to trees.

§ 152.15 Pesticide products required to be registered.

No person may distribute or sell any pesticide product that is not registered under the Act, except as provided in §§ 152.20, 152.25, and 152.30. A pesticide is any substance (or mixture of substances) intended for a pesticidal purpose, i.e., use for the purpose of preventing, destroying, repelling, or mitigating any pest or use as a plant regulator, defoliant, or desiccant. A substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if:

(a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise):

(1) That the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or

(2) That the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or

(b) The substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose (by itself or in combination with any other substance), (2) use for manufacture of a pesticide; or

(c) The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.

Subpart B—Exemptions

SOURCE: 53 FR 15977, May 4, 1988, unless otherwise noted.

§ 152.20 Exemptions for pesticides regulated by another Federal agency.

The pesticides or classes of pesticide listed in this section are exempt from all requirements of FIFRA. The Agency has determined, in accordance with FIFRA sec. 25(b)(1), that they are adequately regulated by another Federal agency.

(a) *Certain biological control agents.* (1) Except as provided by paragraph (a)(3) of this section, all biological control agents are exempt from FIFRA requirements.

(2) If the Agency determines that an individual biological control agent or class of biological control agents is no longer adequately regulated by another Federal agency, and that it should not otherwise be exempted from the requirements of FIFRA, the Agency will revoke this exemption by amending paragraph (a)(3) of this section.

(3) The following biological control agents are not exempt from FIFRA requirements:

(i) Eucaryotic microorganisms, including protozoa, algae and fungi;

(ii) Procaryotic microorganisms, including bacteria; and

(iii) Viruses.

(b) *Certain human drugs.* A pesticide product that is offered solely for human use and also is a new drug within the meaning of FFDCA sec. 201(p) or is an article that has been determined by the Secretary of Health and Human Services not to be a new drug by a regulation establishing conditions of use for the article, is exempt from the requirements of FIFRA. Such products are subject to regulation in accordance with the Federal Food, Drug, and Cosmetic Act and implementing regulations.

§ 152.25 Exemptions for pesticides of a character not requiring FIFRA regulation.

The pesticides or classes of pesticides listed in this section have been determined to be of a character not requiring regulation under FIFRA, and are therefore exempt from all provisions of FIFRA when intended for use, and used, only in the manner specified.

(a) *Treated articles or substances.* An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use.

(b) *Pheromones and pheromone traps.* Pheromones and identical or substantially similar compounds labeled for use only in pheromone traps (or labeled for use in a manner which the Administrator determines poses no greater risk of adverse effects on the environment than use in pheromone traps), and pheromone traps in which those compounds are the sole active ingredient(s).

(1) For the purposes of this paragraph, a pheromone is a compound produced by an arthropod which, alone or in combination with other such compounds, modifies the behavior of other individuals of the same species.

(2) For the purposes of this paragraph, a synthetically produced compound is identical to a pheromone only when their molecular structures are identical, or when the only differences between the molecular structures are between the stereochemical isomer ratios of the two compounds, except that a synthetic compound found to have toxicological properties significantly different from a pheromone is not identical.

(3) When a compound possesses many characteristics of a pheromone but does not meet the criteria in paragraph (a)(2) of this section, it may, after review by the Agency, be deemed a substantially similar compound.

(4) For the purposes of this paragraph, a pheromone trap is a device containing a pheromone or an identical or substantially similar compound used for the sole purpose of attracting, and trapping or killing, target arthropods. Pheromone traps are intended to achieve pest control by removal of target organisms from their natural environment and do not result in increased levels of pheromones or identical or substantially similar compounds over a significant fraction of the treated area.

(c) *Preservatives for biological specimens.* (1) Embalming fluids.

(2) Products used to preserve animal or animal organ specimens, in mortuaries, laboratories, hospitals, museums and institutions of learning.

(3) Products used to preserve the integrity of milk, urine, blood, or other body fluids for laboratory analysis.

(d) *Vitamin hormone products.* Vitamin hormone horticultural products consisting of mixtures of plant hormones, plant nutrients, inoculants, or soil amendments, which meet the following criteria:

(1) The product, in the undiluted package concentration at which it is distributed or sold, meets the criteria of §156.10(h)(1) of this chapter for Toxicity Category III or IV; and

(2) The product is not intended for use on food crop sites, and is labeled accordingly.

(e) *Foods.* Products consisting of foods and containing no active ingredients, which are used to attract pests.

(f) *Natural cedar.* (1) Natural cedar blocks, chips, shavings, balls, chests, drawer liners, paneling, and needles that meet all of the following criteria:

(i) The product consists totally of cedarwood or natural cedar.

(ii) The product is not treated, combined, or impregnated with any additional substance(s).

(iii) The product bears claims or directions for use solely to repel arthropods other than ticks or to retard mildew, and no additional claims are made in sale or distribution. The labeling must be limited to specific arthropods, or must exclude ticks if any general term such as ''arthropods,'' ''insects,'' ''bugs,'' or any other broad inclusive term, is used. The exemption does not apply to natural cedar products claimed to repel ticks.

(2) The exemption does not apply to cedar oil, or formulated products which contain cedar oil, other cedar extracts, or ground cedar wood as part of a mixture.

(g) *Minimum risk pesticides*—(1) *Exempted products.* Products containing the following active ingredients are exempt from the requirements of FIFRA, alone or in combination with other substances listed in this paragraph, provided that all of the criteria of this section are met.

Castor oil (U.S.P. or equivalent)
Cedar oil
Cinnamon and cinnamon oil
Citric acid
Citronella and citronella oil
Cloves and clove oil
Corn gluten meal
Corn oil
Cottonseed oil
Dried blood
Eugenol
Garlic and garlic oil
Geraniol
Geranium oil
Lauryl sulfate
Lemongrass oil
Linseed oil
Malic acid
Mint and mint oil
Peppermint and peppermint oil
2-Phenethyl propionate (2-phenylethyl propionate)
Potassium sorbate
Putrescent whole egg solids
Rosemary and rosemary oil
Sesame (includes ground sesame plant) and sesame oil
Sodium chloride (common salt)
Sodium lauryl sulfate
Soybean oil
Thyme and thyme oil
White pepper
Zinc metal strips (consisting solely of zinc metal and impurities)

(2) *Permitted inerts.* A pesticide product exempt under paragraph (g)(1) of this section may only include inert ingredients listed in the most current List 4A. This list is updated periodically and is published in the FEDERAL REGISTER. The most current list may be obtained by writing to Registration Support Branch (4A Inerts List) Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington DC 20460.

(3) *Other conditions of exemption.* All of the following conditions must be met for products to be exempted under this section:

(i) Each product containing the substance must bear a label identifying the name and percentage (by weight) of each active ingredient and the name of each inert ingredient.

(ii) The product must not bear claims either to control or mitigate microorganisms that pose a threat to human health, including but not limited to